DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service 93554

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

October 18, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2003-01

Mr. Rodney J. Moulder, President
Health Care Manufacturing, Inc.
2146 Pythian
Springfield, MO 65802

Dear Mr. Moulder:

An inspection of your medical device manufacturing operations was conducted on September 3-6, 2002 by an investigator from our office. During this inspection, significant deviations from the Quality System Regulation (Title 21, Code of Federal Regulations (C.F.R.), Part 820) were observed. These deviations cause the X-Ray systems, electrical muscle stimulators, and chiropractic tables manufactured by your firm to be adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 351(h)) in that the methods used in, or the facilities or controls used for their manufacture , packing, storage, or installation are not in conformance with the Quality System Regulation.

Significant deviations include, but are not limited to the following:

1. Failure to establish procedures for management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency to ensure that the quality system satisfies the requirements of 21 C.F.R. Part 820 and the manufacturer's established qual ity policy and objectives, as required by 21 C.F.R. § 820.20(c).

2. Failure to establish and maintain procedures for implementing corrective and preventative action, as required by 21 C.F.R. § 820.100(a). Your firm does not possess procedures for implementing corrective and preventative action that include requirements to analyze work

operations, quality audit reports, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems.

3. Failure to adequately establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, at required by 21 C.F.R. § 820.198(a). There are no written complaint procedures for complaint handling. In addition, complaints involving the possible failure of a device to meet any of its specifications were not evaluated and investigated where necessary.

4. Failure to establish and maintain procedures for servicing medical devices, as required by 21 C.F.R. § 820.200(a) and failure to maintain service reports as required by 21 C.F.R. § 820.200(d). Specifically, documentation of testing and inspection after repairs is not included with service reports for X-Ray systems, Masterstim muscle stimulators, or chiropractic tables.

5. Failure to establish and maintain procedures for controlling non-conforming product, as required by 21 C.F.R. § 820.90(a).

6. Failure to establish and maintain quality system procedures, as required by 21 C.F.R. § 820.20(e).

7. Failure to maintain device history records that contain acceptance records to demonstrate the device is manufactured in accordance with a Device Master Record as required by 21 C.F.R. § 820.184(d).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your firm adheres to current regulations applicable to your operations. The specific violations noted in this letter and in the Form FDA 483 - Inspectional Observations issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing a nd quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your medical device products. Also, other federal agencies are advised of Warning Letters, such as this one, so that they may consider this information when awarding government contracts.

We are in receipt of your FDA 483 response letter dated September 11, 2002. We are in the process of reviewing your response and will forward you our comments under separate cover.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. Please confirm for us what actions described in your September 11, 2002 letter have been completed, and if you have instituted any actions that differ from your previous response. We also ask that you explain how you plan to prevent these deviations from occurring again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District